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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,139	06/12/2001	Peter Allen Revell	23530-0003	9561
909	7590	01/27/2004	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			ROBERT, EDUARDO C	
			ART UNIT	PAPER NUMBER
			3732	22
DATE MAILED: 01/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,139

Applicant(s)

REVELL ET AL.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003 and 19 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-16,18-24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,15,16,18-24 and 26 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 19, 2003 has been entered.

Claim Objections

Claims 18 and 19 objected to because of the following informalities: claims 18 and 19 depend from cancel claim 17. Appropriate correction is required. It is noted that for examination purposes claims 18 and 19 would be considered to be depending from claim 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-13, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz (U.S. Patent 5,188,670).

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Constantz discloses an implant of metal or alloy, e.g. titanium alloy (see col. 7, lines 1-5) having a hydroxyapatite coating that the coating can have incorporated therein a variety of ions, as required (see col. 2, lines 64-68). It is noted that the ions comprise fluorine ions. Constantz discloses the claimed invention except for the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Constantz with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Moreover, with regard to claims 4-6, i.e. up to a maximum depth of 150 nm (claim 4), or up to a maximum depth ranging up to approximately 100 nm (claim 5), or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface (claim 6), it would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Constantz with the ions being incorporated into the surface of the implant up to a maximum depth of 150 nm, or up to a maximum depth ranging up to approximately 100 nm, or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claim 10, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Constantz with the ions being magnesium or manganese, or zinc, or silicon, since it has been held to be within the general skill of a worker in the art to select a known material on

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the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 1, 2, 4-13, 15, 16, 18-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Natasi et al. (U.S. Patent 5,817,326).

Natasi et al. disclose an implant having a hydroxyapatite coating that the coating can have incorporated therein a ion (see abstract). Natasi, et al. disclose that any ions might be utilized in the ion implantation process (see col. 5, lines 25-27), thus this statement include ions of groups IIA, IVA, VIIA and transition elements. Natasi et al. disclose that the ions are incorporated via ion beam implantation. Natasi et al. disclose the claimed invention except for the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Natasi et al. with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Moreover, with regard to claims 4-6 and 18-20, i.e. up to a maximum depth of 150 nm (claims 4 and 18), or up to a maximum depth ranging up to approximately 100 nm (claims 5 and 19), or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface (claims 6 and 20), it would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Natasi et al. with the ions being incorporated into the surface of the implant up to a maximum depth of 150 nm, or up to a maximum depth ranging up to approximately 100 nm, or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions

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per cm² of the surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claim 10, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Natasi et al. with the ions being magnesium or manganese, or zinc, or silicon, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. However, the following arguments are addressed:

In response to applicant's argument that the examiner did not establish a *prima facie* case of obviousness, it is noted that the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale to modify may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or **legal precedent established by prior case law**. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In response to applicant's argument that Constantz discloses that the lowest depth that can be considered is 2000 nm, it is noted that Constantz only discloses that the coatings **may be** as thin as about 2 microns. This does not mean that can not be less as suggested by applicant.

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In response to applicant's argument that applicant's invention is directed to a maximum ion depth of 200 nm recited and that this is critical, it is noted that applicant specification discloses in page 3, line 33, through page 4, line 1, "Whilst this is the preferred maximum depth of ions, it is possible to implant ions to greater depths, for example 1000 nm". Thus, it is clear that the range to 200 nm is just a preferred range and it can be varied depending on the intended use.

Moreover, applicant has not provide any convincing showing that these, i.e. ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, or 150 nm, or 100 nm, or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface, are nothing more than optimum or workable values as asserted by the examiner.

Applicant has not provided any showing that such limitations are "critical". In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973). **Mere arguments by counsel cannot take the place of evidence.** In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

In response to applicant's argument that Natasi et al. has to have a coating thickness of between 50 and $200\mu\text{m}$ and that this is essential to the operation of the implant of Natasi et al., it is noted that applicant is assuming this and Natasi et al. clearly disclose "The foregoing description of the invention has been presented for purposes of illustration and description and **is not intended to be exhaustive or to limit the invention to the precise form disclosed**, and obviously many modifications and variations are possible" (emphasis added by examiner) (see Natasi et al. col. 5, lines 21-25).

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Allowable Subject Matter

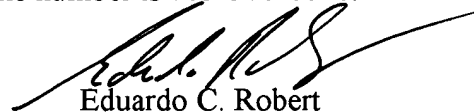
Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.